VELOZ 40

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for VELOZ 40 (Rabeprazole Gastro- Resistant Tablets I.P. 40 mg**)**

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Rabeprazole belongs to a class of antisecretory compounds (substituted benzimidazoles proton-pump inhibitors) that do not exhibit anticholinergic or histamine H2-receptor antagonist properties, but suppress gastric acid secretion by inhibiting the gastric H+, K+ATPase at the secretory surface of the gastric parietal cell. Because this enzyme is regarded as the acid (proton) pump within the parietal cell, rabeprazole has been characterized as a gastric proton-pump inhibitor. Rabeprazole blocks the final step of gastric acid secretion. In gastric parietal cells, rabeprazole is protonated, accumulates, and is transformed to an active sulfenamide. When studied in vitro, rabeprazole is chemically activated at pH 1.2 with a half-life of 78 seconds. It inhibits acid transport in porcine gastric vesicles with a half-life of 90 seconds.

THERAPEUTIC INDICATION: It is indicated for the treatment of gastroesophageal reflux disease (acid reflux) and Peptic ulcer disease.

DOSAGE AND ADMINISTRATION: As directed by physician. One Tablet once daily. Tablet should be swallowed whole. Do not crush or chew the tablet.

CONTRAINDICATION: Rabeprazole is contraindicated in patients with known hypersensitivity to rabeprazole, substituted benzimidazoles or to any component of the formulation. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, acute interstitial nephritis, and urticaria. For information about contraindications of antibacterial agents (clarithromycin and amoxicillin) indicated in combination with Rabeprazole.

WARNINGS & PRECAUTIONS:

Presence of Gastric Malignancy: Symptomatic response to therapy with rabeprazole does not preclude the presence of gastric malignancy. Patients with healed GERD were treated for up to 40 months with rabeprazole and monitored with serial gastric biopsies. Concomitant Use with Warfarin: There have been reports of increased INR and prothrombin time in patients receiving a proton pump inhibitor and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Acute Interstitial Nephritis: Acute interstitial nephritis has been observed in patients taking PPIs including Rabeprazole. Cyanocobalamin (vitamin B-12) Deficiency: Daily treatment with any acid-suppressing medications over a long period of time (e.g., longer than 3 years) may lead to malabsorption of cyanocobalamin (vitamin B-12) caused by hypo-or achlorhydria. Clostridium difficile Associated Diarrhea: Published observational studies suggest that PPI therapy like Rabeprazole may be associated with an increased risk of Clostridium difficile associated diarrhea, especially in hospitalized patients. This diagnosis should be considered for diarrhea that does not improve. Bone Fracture: Several published observational studies in adults suggest that PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. Hypomagnesemia: Hypomagnesemia, symptomatic and asymptomatic, has been reported rarely in patients treated with PPIs for at least three months, in most cases after a year of therapy. Concomitant Use of Rabeprazole with Methotrexate : Literature suggests that concomitant use of PPIs with methotrexate may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to

methotrexate toxicities. In high-dose methotrexate administration, a temporary withdrawal of the PPI may be considered in some patients.

DRUG INTERACTION:

Presence of Gastric Malignancy: Symptomatic response to therapy with rabeprazole does not preclude the presence of gastric malignancy. Concomitant Use with Warfarin: Steady state interactions of rabeprazole and warfarin have not been adequately evaluated in patients. There have been reports of increased INR and prothrombin time in patients receiving a proton pump inhibitor and warfarin concomitantly. Acute Interstitial Nephritis: Acute interstitial nephritis has been observed in patients taking PPIs including Rabeprazole. Cyanocobalamin (vitamin B-12) Deficiency: Daily treatment with any acid-suppressing medications over a long period of time (e.g., longer than 3 years) may lead to malabsorption of cyanocobalamin (vitamin B-12) caused by hypo-or achlorhydria. Clostridium difficile Associated Diarrhea: Published observational studies suggest that PPI therapy like Rabeprazole may be associated with an increased risk of Clostridium difficile associated diarrhea, especially in hospitalized patients. This diagnosis should be considered for diarrhea that does not improve. Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Bone Fracture: Several published observational studies in adults suggest that PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer). Hypomagnesemia: Hypomagnesemia, symptomatic and asymptomatic, has been reported rarely in patients treated with PPIs for at least three months, in most cases after a year of therapy. Serious adverse events include tetany, arrhythmias, and seizures. For patients expected to be on prolonged treatment or who take PPIs with medications such as digoxin or drugs that may cause hypomagnesemia (e.g., diuretics), healthcare professionals may consider monitoring magnesium levels prior to initiation of PPI treatment and periodically. Concomitant Use of Rabeprazole with Methotrexate.

ADVERSE REACTIONS: *Common (affect less than 1 in 10 people):* Infections, Difficulty sleeping, Headache or feeling dizzy, Cough, runny nose or sore throat (pharyngitis), effects on your stomach or gut such as stomach pain, diarrhoea, wind (flatulence), feeling sick (nausea), being sick (vomiting) or constipation, aches or back pain, weakness or flu-like symptoms, benign polyps in the stomach. *Uncommon (affect less than 1 in 100 people):* Feeling nervous or drowsy, Chest infection (bronchitis), Painful and blocked sinuses (sinusitis), Dry mouth, Indigestion or belching, Skin rash or redness, Muscle, leg or joint pain, Fractures of the hip, wrist and spine, Bladder infection (urinary tract infection), Chest pain, Chills or fever, Changes in how your liver is working (shown in blood tests) *Rare (affect less than 1 in 1,000 people:* Loss of appetite (Anorexia), Depression, Hypersensitivity (includes allergic reactions), Visual disturbance, Sore mouth (stomatitis) or taste disturbance, Upset stomach or stomach pain, Liver problems including yellowing of your skin and whites of your eyes (jaundice), Itchy rash or blistering skin, Sweating, Kidney problems, Weight gain, Changes in white blood cells (shown in blood tests) which may result in frequent infection, Reduction in blood platelets resulting in bleeding or bruising more easily than normal, *Other possible side effects (unknown frequency:* Acute kidney injury, Breast swelling in men, Fluid retention, Inflammation of the gut (leading to diarrhoea), Low blood levels of sodium which can cause tiredness and confusion, muscle, Twitching, fits and coma, Patients who have previously had liver problems may very rarely get encephalopathy (a brain disease)" and rash, possibly with pain in the joints.

Manufactured BY:
Torrent pharmaceuticals Ltd.

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(Additional information is available on request)